The following is a Korea market brief for the AACC Clinical Lab Expo 2005 in Orlando.

Name of Country/Region ___Republic of Korea____________________

1. Population
   a. Total population __48 Mil.__
   b. % having access to quality healthcare _*_%
      * This depends on the definition of quality healthcare. The entire Korean population is able to access fundamental healthcare services under the National Health Insurance (NHI) system, which pays for 80% of insured services. For certain services, such as cancer treatment, NHI sets prices but does not reimburse for these services, i.e., these services are 100 percent patient-paid.

2. Who Pays for Healthcare? What Percentage?
   a. Government 44.4 %
   b. Private Insurance 11.5 %
   c. Patient Out-of-Pocket 44.1 %

3. Number of testing facilities (latest data from the Ministry of Health and Welfare)
   a. Hospital
      i. Public: 87
      ii. Private: 842
      iii. Government: 46
   b. Independent labs (Commercial): less than 20
   c. Physician Offices (clinics): 23,299
   d. Pharmacies: 17, 823
   e. Other: 2 (Tuberculosis Hospital)

4. Import statistics and trends of clinical laboratory products (Estimated in 2004)
   a. From U.S. : $ 77.0 million
   b. From ROW: $ 51.4 million from European countries (Switzerland, Germany, etc.)

5. Barriers to market entry
   a. Regulatory:
      Pre-market Approval:
      All diagnostic clinical laboratory products (instruments and reagents) are required to obtain marketing clearance from the Korea Food & Drug Administration (KFDA) before they can be manufactured in or imported into Korea. For example, a clinical lab instrument undergoes one of two different regulatory pathways, depending on its classification under the Korean regulatory system. KFDA requires pre-market notification for class I devices and pre-market approval for class II, III, and IV devices. Most clinical lab instruments currently in the market fall under class I or

class II. Since KFDA issues product licenses only to locally based firms, all foreign suppliers must submit required documentation and receive necessary approvals through their Korean importers or through a Korea-registered subsidiary of the US supplier.

b. Duties: Instruments: 8% (FOB)
Reagents for diagnostics: 0% – 2.5% (FOB)
Reagents for research: 8% (FOB)

c. Domestic: Domestic manufacturers are required to obtain the same marketing clearance.

d. Procurement practices: Most general and big hospitals (more than 250 beds) purchase through bidding, while small hospitals/clinics purchase through private contracts.

e. Distribution systems:
Clinical laboratory products are distributed through local distributors or commissioned agents. A local distributor or commissioned agent may directly cover the whole country on an exclusive basis. A master distributor may contract with other regional sub-dealers.

Major international suppliers work directly on advertising, make direct contact with doctors, and provide them with technical assistance. Meanwhile, sales are made through their Korean distributors or subsidiaries. Most Korean distributors working with the major international firms maintain close relationships with senior doctors at major hospitals.

6. Contact lists
a. Domestic IVD Manufactures:
There is no local manufacturer of IVD instruments, but there are about 100 reagent makers in Korea. The top three Korean reagent makers are:

1) YD - Diagnostics
Address: 2F., Kukdong Building A-dong
228-8, Jamsil-dong, Songpa-ku
Seoul
Phone: 82-2-2233-3531
Fax: 82-2-2233-5687
Website: www.yd-diagnostics.com

2) LG Life Sciences
Address: 601, Yongjae-dong
Iksan, Junbuk
Phone: 82-63-830-4250

Fax:	82-063-830-4261
Website:	www.lgls.co.kr

3) Green Cross

Add:	303 Bojung-ri, Gusung Yong In, Kyonggi-do
Phone:	82-31-260-9300
Fax:	82-31-260-9405
Website:	www.kgcc.co.kr

b. Trade and Professional Associations:

1) The Korean Society of Laboratory Medicine

Add:	Rm. 601, Korean Medical Association Bldg. 302-75, Ichon 1-dong, Yongsan-ku Seoul
Phone:	82-2-795-9914
Fax:	82-2-790-4760
Website:	www.kslm.org

2) The Korean Association of Medical Technologies

Add:	2F., Myungshil Bldg. 165-15, Samsung-dong, Kangnam-ku Seoul
Phone:	82-2-508-5591
Fax:	82-2-508/5592
Website:	www.kamt.or.kr

c. Information sources:

Commercial Service Korea
U.S. Embassy, Seoul

Add:	32, Sejong-ro, Chongro-ku Seoul
Contact:	Helen Peterson, Commercial Attaché (email: Helen.peterson@mail.doc.gov) Yoonshil Chay, Senior Commercial Specialist (email: yoon.shil.chay@mail.doc.gov)
Phone:	82-2-397-4439
Fax:	82-2-737-5357

d. Distributors

Since Korean distributors handle specific product lines, CS Korea can provide a list of distributors, through CS Korea’s fee-based programs.

7. Market Opportunities

Total market demand for clinical lab products in Korea is forecast to reach approximately US$ 214 million in 2005 and is expected to grow 5-10% annually for the next three years. Among them, the market for In Vitro Diagnostic (IVD) products accounts for about 95% or $203 million (US$1=W1200). Imports of IVD products represent about 60% of the total market demand for IVD products. According to industry, IVD instruments are nearly 100 percent imported, while around 60 percent of reagents in Korea are imported. Among the total imports, U.S. products account for about 60% and EU products account for 40%. Major foreign key players in the Korean market are Roche (Switzerland), Abbott (U.S.), Bayer (Germany), Johnson & Johnson (U.S.), and Beckman (U.S.). Big general hospitals, which have more than 250 beds, use foreign clinical lab products (instruments & reagents) mostly, which account for more than 90% of their total use, while small clinics use domestic products (mostly reagents for a limited range of testing).

8. Size of IVD market in units and US$: $203 million (US$1=W1200, 230 billion won)
   a. Instruments: $ 46.7 M
      i. Chemistry Units 200-220 $ 15.9M
      ii. Hematology Units 200-220 $ 7.9M
      iii. Microbiology Units 200-220 $ 18.2M
      (including immunology)
      iv. Others $ 4.7M

   b. Reagents: $ 156.3
   * c. Point of Care Testing Units ______ $ _____
   * d. Self testing Units ______ $ _____

** Industry has no estimates, but sources say that the market is small and growth is limited. Point of Care Testing and Self-testing products could fall under either Instruments or Reagents, according to industry.